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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284
27777	7590	01/26/2006	EXAMINER	GEORGE, KONATA M
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/697,840	WYNN ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) 5-12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 1-22 are pending in this application.

### ***Drawings***

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on February 11, 2004 and August 31, 2005 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 recites the limitation "insoluble film-forming polymer and enteric polymer" in lines 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) and of Barry et al. (US 5,055,306).

Ratnaraj et al. discloses a novel suspension system containing acetaminophen (col. 2, lines 46-55). Column 4, lines 1-2 teach the system is suitable from suspending acetaminophen powder. The suspending system (examiner relates it to the vehicle as claimed by applicant) comprises xanthan gum and a mixture of microcrystalline cellulose and sodium carboxymethylcellulose (col. 2, lines 51-53). Table 1 of columns 6 and 7 disclose the addition of water to the vehicle, a glycol such as propylene glycol, sweeteners and flavoring agents. The prior art does not teach the particles being coated with a controlled release composition, the composition having a therapeutic effect of least about 8 hours and the NSAID is a propionic acid derivative.

Singh et al. discloses a pharmaceutical suspension system comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose (col. 1, lines 4-12). Column 2, lines 30-35 teach that the active compounds can be non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic

drugs such as acetaminophen. Of the NSAIDs for use in the system propionic acid derivatives can be employed (col. 3, lines 3-7). Preservatives, sweeteners, and flavoring agents can be used in the system (col. 4, lines 5-10). The various examples in columns 4-7 teach the concentrations of the drug as about 3.20% and at least 40% water.

Barry et al. discloses sustained release formulations of pharmaceutically active substances. The formulations comprise a core and a coating. Examples of the active agents can be non-steroidal anti-inflammatory drugs (NSAIDs) (col. 7, lines 3-27). Column 5, lines 64-65 teach that the formulation for the granules provides a sustained release over a period of 12 hours. Column 6, line 49 through column 7, line 2 teaches examples of the coating such as acrylic polymers sold under the name Eudragit<sup>TM</sup>.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Ratnaraj et al. (a suspension of acetaminophen) in view of Singh et al. (a suspension of NSAIDs) and of Barry et al. to disclose the claimed invention. One of ordinary skill would use the coating compositions of Barry et al. to coat the drugs of Ratnaraj et al. or Singh et al. for the purpose of providing a sustained release profile for the active agent. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

***Conclusion***

5. Claims 1-22 are rejected.

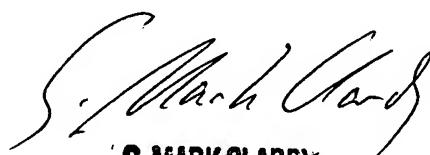
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
S. MARK CLARDY  
PATENT EXAMINER  
GROUP 1200  
16/16